APR 1 3 2001

K010781

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Name:	Scott T. Erickson Regulatory Affairs Specialist
Address:	3M ESPE Dental Products 3M Center, Building 260-2B-12 St. Paul, MN 55144-1000
Telephone:	651-736-9883
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Trade Name:	3M™ ESPE™ HAUR
Common Names:	Tooth shade resin material
Classification Name:	Tooth shade resin material (21 CFR §872.3690)
Predicate Devices:	3M™ Dent II System XRV™ Herculite® TPH™ Spectrum™ Esthet •X™ Point 4

3M™ ESPE™ HAUR restorative material is a visible-light activated, radiopaque, restorative composite. It is designed for use in direct anterior and posterior restorations, core build-ups, splinting, and indirect restorations including inlays, onlays and veneers.

3M™ ESPE™ HAUR is substantially equivalent to the 3M™ Dent II System (K981647) in terms of indications for use, chemical ingredients and safety. The data from toxicity tests conducted and evaluated on the 3M™ Dent II System, consideration of the potential intrinsic toxicity of individual components, predicted patient exposure and past patient experience with 3M™ Dent II System support the assessment that 3M™ ESPE™ HAUR is safe for its intended use.

3M™ ESPE™ HAUR is substantially equivalent to XRV™ Herculite®, TPH™ Spectrum™, Esthet •X™ and Point 4 in terms of indications for use and technological characteristics as shown by laboratory bench test data provided in this 510(k) submission (i.e., Watts Shrinkage, Compressive Strength, Diametral Tensile Strength, Wear Resistance, Water Sorption, Thermal Expansion Coefficient, Fracture Toughness, Polish Retention and Flow).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 2001

Mr. Scott Frickson
Regulatory Affairs Specialist
3M Company
Dental Products Division
3M Center, Building 260-2B-12
St. Paul, Minnesota 55144

Re: K010781
Trade/Device Name: 3M™ ESPE™ HAUR
Regulation Number: 872.3690
Regulatory Class: II
Product Code: EBF
Dated: March 14, 2001
Received: March 15, 2001

Dear Mr. Erickson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devcies
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010781

510(k) Number: K010781

Device Name: 3M™ ESPE™ HAUR

Indications for Use:

a) Direct anterior restorations including:
   i) Class III, IV, V and VI
   ii) Veneers
   iii) Incisal edge repair
b) Direct posterior restorations including
   i) Class I or II or V
   ii) Sandwich technique with glass ionomer resin material
   iii) Cusp buildups
c) Core Buildups
d) Splinting
e) Indirect anterior and posterior restorations including:
   i) Inlays
   ii) Onlays
   iii) Veneers

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

(Division Sign-Off) Pamela Scott for Susan Runner
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010781